K111424

JUL 29 2011

510(k) SUMMARY

July 11, 2011

CONTACT:

Judi Smith
Judi Smith, LLC
P.O Box 103
Baldwin, MD 21013

NAME OF DEVICE:

Trade Name:	VACUETTE® PREMIUM Safety Needle System Tube-Touch
Common Names/Descriptions:	Tube holder and safety needle
Classification Name:	Needle, Hypodermic, Single Lumen

PREDICATE DEVICE: VACUETTE® PREMIUM Safety Needle System (K072602)

DEVICE DESCRIPTION:

INTENDED USE:
The VACUETTE® PREMIUM Safety Needle System Tube-Touch is used in routine venipuncture procedures. The Needle System is designed with an integrated, multiple sample needle and safety shield. The safety shield is automatically activated and released upon insertion of the first blood collection tube and covers the needle immediately following blood collection from patient. The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.

DESCRIPTION:
The VACUETTE® PREMIUM Safety Needle System Tube-Touch is a single-use, sterile needle system, non-toxic, designed with an integrated, multiple use drawing needle and safety shield to provide protection against needlestick injury during venipuncture. This device has no components made of dry natural rubber.

SUBSTANTIAL EQUIVALENCE:
This Special 510(k) is intended to update the FDA's 510(k) file for non-significant changes made to the VACUETTE® PREMIUM Safety Needle System. The VACUETTE® PREMIUM Safety Needle System Tube-Touch which is the subject of this submission is substantially equivalent to the VACUETTE® PREMIUM Safety Needle System (K072602) in intended use and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MedPro Safety Products, Incorporated
C/O Ms. Judi Smith
Principal
P.O. Box 103
Baldwin, Maryland 21013

JUL 29 2011

Re: K111424
Trade/Device Name: Vacuette® Premium Safety Needle System Tube-Touch
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI, MEG
Dated: July 11, 2011
Received: July 12, 2011

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/ CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111424

Device Name: VACUETTE® PREMIUM Safety Needle System Tube-Touch

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Prescription Use __x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner for RC

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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